08/177,920 01/06/94 ALIZON

M 3495.001017
EXAMINER
RAILEY, J
ART UNIT | PAPER NUMBER
18M2/1207 13

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1804
DATE MAILED:
12/07/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ ~~days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 11-34 are pending in the application.
   Of the above, claims 19-34 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 11-18 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☒ been filed in parent application, serial no. 07/158,652; filed on 2/22/88.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1804.

Applicant's election without traverse of Group I, claims 11-18, in Paper No. 11, received 28 September 1994 is acknowledged.

Claims 19-34 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 11.

It is noted that applicant's response refers to a title different from that on the current application. Applicant indicates at page 1 of paper No. 11 that the title has been amended. However, the record does not indicate that applicant has directed the amendment of the title of the invention.

Claims 11-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-22 of copending application Serial No. 08/202,239. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the identical nucleic acid sequences to be used as probes in the diagnostic hybridization methods of the instant application. It appears that application Serial Nos.

08/202,236 and 08/177,920 were filed by applicant as divisional applications from the parent application Serial No. 07/158,652. There is no evidence that the PTO has set forth a restriction requirement between the nucleic acids of application Serial No. 08/202,239 and the methods of use of those nucleic acids as probes in application Serial No. 08/177,920.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 11-18 are rejected under 35 U.S.C. § 101 because the invention as claimed lacks patentable utility and as disclosed is not demonstrated operable.

Applicant discloses the complete nucleic acid sequence of the genome of LAV, now known as a specific isolate of HIV-1. The sequence is translated into each of three potential reading frames in order to

locate all significant open reading frames and assign gene locations. Applicant's claims are drawn to *in vitro* diagnostic methods for detecting the presence or absence of nucleic acid of HIV-1 in a biological sample by using specific cloned nucleic acids as probes. These probes may also be labeled with any of several types of labels. Kits comprising this cloned nucleic acid to be used in the *in vitro* diagnostic assay are also claimed. The nucleic acids used as probes in the diagnostic assays are ORF-Q, ORF-R, ORF-1, ORF-2, ORF-3, ORF-4 and ORF-5. Applicant's preliminary amendment, paper No. 6, filed 6 January 1994, at page 40 cites the specification at pages 12, line 34 through page 13, line 5; and page 14, lines 17-32 for support for the claims. However, the specification as filed provides no utility for the claimed diagnostic methods which use these nucleic acids as a probe. It is not demonstrated that the nucleic acids hybridize specifically with HIV-1 to detect the presence or absence of this virus in a biological sample. No specific conditions or methods are given which would allow discrimination between HIV-1 and other retroviruses, such as HTLV-I, HTLV-II or HIV-2 when using the claimed probe. How specific is the probe for any given variant of HIV-1; will it detect strains other than LAV? How are these various "biological samples" to be prepared for the hybridizations such that HIV-1 is detected specifically, reproducibly and accurately? Consequently, the

invention as claimed has no demonstrated patentable utility and also has not been demonstrated operable.

Applicant is provided with a reference by Hahn et al. [Nature 312:166-169 (1984)] which demonstrates that at the time of the filing of the instant application, it was known that cross-hybridization indeed does occur between the sequences of HIV and members of the HTLV family; even at stringent conditions. See Figure 4.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to teach adequately how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

As noted above in the grounds of rejection under 35 U.S.C. § 101, applicant has not demonstrated that the invention as claimed functions as an in vitro diagnostic assay to detect the absence or presence of HIV-1 in a biological sample. The specification as filed provides no guidance as to how the ORF probes would be used to detect HIV specifically. Nor does the specification teach the hybridization

conditions under which the methods are to be used. Likewise, the composition of the kits to effect such specific diagnostic assays is not described. What are the "reagents" to be used and what comprises the "biological reference sample" to enable a useful kit?

Claims 11-18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey, whose telephone number is (703) 308-0281. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Elizabeth C. Weimar, can be reached at (703) 308-0254. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JACQUELINE STONE
PRIMARY EXAMINER
ART UNIT 1804

Johnny F. Railey II, Ph.D.
November 15, 1994